

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
DOMINICK PAPANDREA, <i>et al.</i> , Plaintiffs, vs. ABBVIE, INC., <i>et al.</i> , Defendants.	Civil Action No.: 1:14-cv-08948

**BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS
OF CULLEY C. CARSON, III, M.D. UNDER FED. R. EVID. 702.**

Defendants have designated Culley C. Carson, M.D., a board-certified urologist, to offer general and case-specific opinions concerning hypogonadism and AndroGel. However, Dr. Carson's opinions wander far beyond his qualifications in urology. For example, Dr. Carson opines on the significance (or lack thereof) of various potential cardiovascular risk factors, including AndroGel, that may have contributed to or caused Mr. Papandrea's myocardial infarction. Based on his own conclusion that AndroGel is not a cardiovascular risk factor, Dr. Carson also opines that the pre-2015 AndroGel labeling contained enough information for Mr. Papandrea's prescribing physician to fully weigh the risks and benefits of AndroGel before he prescribed it.

As decisions in this Circuit make clear, expert opinions that implicate a particular field of medicine—here cardiology—must be left to experts in that area. Dr. Carson is a urologist, not a cardiologist or a labeling expert and he is not otherwise qualified to offer such opinions. Plaintiffs therefore respectfully ask the Court to limit Dr. Carson’s testimony to his area of expertise: urology.

I. BACKGROUND

A. Dr. Carson’s Qualifications.

Dr. Carson is a board-certified urologist. (Ex. 1, Carson General Report, at 1; Ex. 3, Carson Dep., May 14, 2018, at 18:9-11.) As a urologist, Dr. Carson’s practice is primarily focused on men’s sexual health and the treatment of erectile dysfunction. (Ex. 3, at 59:22-24, 60:1-8.) Dr. Carson is neither a board-certified cardiologist nor an expert in cardiology or cardiovascular disease. (*Id.* at 70: 3-10, 71:4-10.) He has never been consulted concerning the cause of a patient’s myocardial infarction (*id.* at 71:15-18) and defers to cardiologists on such issues because he is himself not capable of making such a determination (*id.* at 84:5-14). Dr. Carson also defers to cardiologists to determine whether it would be safe to prescribe AndroGel to a patient with known vascular conditions or complications. (*Id.* at 394:12-18.) Similarly, Dr. Carson is not a regulatory expert and has no experience in drafting warnings, precautions, or other sections contained in the prescribing information that accompanies prescription drugs. (*Id.* at 335:9-17.)

B. Dr. Carson’s Opinions.

Abbvie retained Dr. Carson to provide general opinions “concerning the diagnosis and treatment of men with hypogonadism, and the clinical benefits and risks

of TRT, including AndroGel” (General Rep., at 4), as well as case-specific opinions regarding whether Mr. Papandrea “was appropriately diagnosed and treated with AndroGel 1.62%” (Ex. 2, Carson Case Specific Rep., at 1.)

His reports go further, however, and include opinions addressing the significance of various cardiovascular risk factors he claims played a role in causing Mr. Papandrea’s myocardial infarction in 2012. He also opines about the adequacy of the AndroGel labeling at the time Mr. Papandrea took it. For example, he holds the following opinions based on a reasonable degree of medical and scientific certainty:

AndroGel’s risk/benefit profile has always been positive and remains so today, for hypogonadal men. The positive risk/benefit profile is supported by numerous high-quality clinical and epidemiological studies. While a handful of studies reported a potential risk of CV events associated with TRT, those studies have been widely discredited (including by the FDA and many in the medical community). Importantly, more recent and more scientifically sound studies have failed to demonstrate any association (let alone a causal relationship), and, in fact, several suggest that TRT may be cardio-protective. (General Rep., at 4; see *also* Specific Report at 6.)

Mr. Papandrea had many risk factors for cardiovascular disease including being overweight, advanced age, hypertension, hyperlipidemia, elevated glucose, history of tobacco use, and family history of coronary artery disease. (Specific Rep., at 5-6.)

The AndroGel 1.62% label adequately disclosed sufficient information regarding risks, including potential increases in hematocrit levels and the possible side effects of clots, to enable Dr. Cascarina to determine whether to prescribe Mr. Papandrea with AndroGel. (Specific Rep., at 3-4.)

Dr. Cascarina had the information necessary to determine whether the potential benefits of AndroGel would outweigh any potential risks to Mr. Papandrea given his medical history, symptoms and age. (Specific Rep., at 3.)

Dr. Carson was deposed in this case on May 14, 2018. (See *generally* Ex. 3.)

II. ARGUMENT

To assess an expert's qualifications under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), courts compare “the area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony.” *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010). An expert is not qualified merely because he is an expert in any particular area: his area of expertise must correspond with his testimony. See *id.*

“Simply because a doctor has a medical degree does not make him qualified to opine on all medical subjects.” *Id.* at 617. In fact, a doctor who offers testimony outside his area of expertise may not be qualified to do so. See, e.g., *Hall v. Flannery*, 840 F.3d 922, 925, 929-30 (7th Cir. 2016) (finding a pediatric neurologist unqualified to testify about a “heart-related issue” as a cause of death); *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 704-05 (finding a pulmonologist unqualified to offer causation testimony requiring expertise in toxicology); *Baldonado v. Wyeth*, No. 04 C 4312, 2012 WL 1597384, at *5-6 (N.D. Ill. May 7, 2012) (holding a radiologist not qualified to offer causation testimony regarding breast cancer).

A. Dr. Carson Is not Qualified to Offer Expert Opinions Regarding the Potential Causes of Myocardial Infarctions Generally or the Myocardial Infarction Suffered by Plaintiff Specifically.

Dr. Carson's reports confirm he intends to offer opinions beyond the scope of his expertise in urology. While Dr. Carson is a medical doctor, *Gayton*, *Hall*, *Higgins*, and *Baldonado* confirm that being a doctor alone does not qualify an expert to testify to issues outside of his area of expertise. While Dr. Carson is a qualified urologist; he is not qualified to testify as to the significance of cardiovascular risk factors or to the

potential causes of Mr. Papandrea's myocardial infarction. For the same reasons, he is also not qualified to offer opinions about whether AndroGel can cause myocardial infarctions. Such opinions require expertise in *cardiology*, which he does not have.

Moreover, opinions regarding the significance of cardiovascular risk factors, including AndroGel, go to the issue of causation. As Dr. Carson testified already, he will not address causation at trial. (Ex 3, at 362:17-21.) That is because he has no experience determining the cause of a myocardial infarction. In his practice, he defers to cardiologists to perform such an analysis. That is what should happen here.¹

Defendants may argue Dr. Carson is qualified to offer these opinions because he discusses the risks and benefits set forth in the AndroGel labeling with his urology patients. However, mere discussions with patients as to the possible risks and benefits of AndroGel do not transform Dr. Carson into an expert qualified to testify about the significance of cardiovascular risk factors or the causes of myocardial infarctions

B. Dr. Carson Is not Qualified To Offer Expert Opinions Regarding the Adequacy of the AndroGel Label at the Time of Plaintiff's Myocardial Infarction.

Dr. Carson should also be precluded from testifying that the 2012 AndroGel label contained sufficient information for Dr. Cascarina and Mr. Papandrea to fully weigh of the risks and benefits of AndroGel treatment. This opinion also impermissibly encroaches on causation issues requiring expertise in cardiology and federal drug labeling. This is particularly true because the sole foundation for this opinion is his

¹ Notably, Defendants will not be prejudiced by the limitation of Dr. Carson's opinions to urology as these opinions are cumulative of opinions Dr. William White plans to offer at trial on Defendants' behalf.

opinion that AndroGel does not cause cardiovascular injuries—an opinion he is not qualified to express under *Daubert*. (Ex. 3, at 343:22-350:17.)

III. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court limit Dr. Carson's testimony to his area of expertise—urology—and preclude him from offering any opinions that require expertise in cardiology or drug labeling.

Dated: June 14, 2018

Respectfully submitted,

COHEN & MALAD, LLP

/s/ Edward B. Mulligan V

Gregory L. Laker

Jeff S. Gibson

Edward B. Mulligan V

One Indiana Square, Suite 1400

Indianapolis, Indiana 46204

Phone: (317) 636-6481

Fax: (317) 636-2593

Email: glaker@cohenandmalad.com

Email: jgibson@cohenandmalad.com

Email: nmulligan@cohenandmalad.com

T. Matthew Leckman

POGUST BRASLOW & MILLROOD, LLC8

Tower Bridge

161 Washington Street, Suite 940

Conshohocken, PA 19428

Phone: (610) 941-4204

Fax: (610) 941-4245

Email: mleckman@pbmattorneys.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF System for filing and service to all parties/counsel registered to receive copies in this case.

/s/ Edward B. Mulligan V
Edward B. Mulligan V